

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A., INC.,	:	
	:	
Plaintiff/Counterclaim-Defendant,	:	
	:	
v.	:	Civil Action No. 1:13-cv-00493-SLR
	:	
AMNEAL PHARMACEUTICALS, LLC,	:	
	:	
Defendant/Counterclaimant.	x	

**DEFENDANT AMNEAL PHARMACEUTICALS, LLC'S,
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS
TO PLAINTIFF'S THIRD AMENDED COMPLAINT**

Defendant Amneal Pharmaceuticals, LLC ("Amneal"), by and through undersigned counsel, answers the Third Amended Complaint for Patent Infringement ("Complaint") of Plaintiff Takeda Pharmaceuticals U.S.A. ("Takeda") as follows:

I. ANSWER

NATURE OF THE ACTION

1. Amneal admits that Takeda has filed an action for purported patent infringement of U.S. Pat. Nos. 7,619,004 ("the '004 patent"); 7,601,758 ("the '758 patent"); 7,820,681 ("the '681 patent"); 7,915,269 ("the '269 patent"); 7,964,647 ("the '647 patent"); 7,964,648 ("the '648 patent"); 7,981,938 ("the '938 patent"); 8,093,296 ("the '296 patent"); 8,093,297 ("the '297 patent"); 8,097,655 ("the '655 patent"); 8,415,395 ("the '395 patent"); 8,415,396 ("the '396 patent"); 8,440,721 ("the '721 patent"); and 8,440,722 ("the '722 patent"). Amneal further admits that it has filed Abbreviated New Drug Application ("ANDA") No. 20-4711 with the United States Food and Drug Administration ("FDA"). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 1 of the Complaint.

THE PARTIES

2. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint, and therefore denies them.

3. Amneal admits that Amneal Pharmaceuticals, LLC is a corporation organized under the laws of the State of Delaware, having a principal place of business at 440 U.S. Highway 22 East, Suite 104, Bridgewater, New Jersey 08807. Amneal admits that it is in the business of manufacturing, marketing and selling high quality pharmaceutical products in the United States, including the State of Delaware. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 3 of the Complaint.

JURISDICTION AND VENUE

4. Paragraph 4 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal does not contest that this Court has jurisdiction over the subject matter of the Complaint.

5. Paragraph 5 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal admits that it is not contesting the personal jurisdiction of this Court over Amneal Pharmaceuticals, LLC, solely for the purposes of this litigation. Amneal admits that it is a Delaware Corporation and that it has previously submitted to the personal jurisdiction of this Court on limited bases, and that it has previously asserted counterclaims in other actions within the District. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 5 of the Complaint.

6. Paragraph 6 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal does not contest that venue is proper.

STATEMENT OF FACTS RELEVANT TO ALL COUNTS

7. On information and belief, Amneal admits that according to publically available FDA information, COLCRYS[®] is indicated for the “prophylaxis and treatment of gout flares in adults” and “Familial Mediterranean Fever in adults and children 4 years or older.” Except as expressly admitted, Amneal denies the remaining allegations in paragraph 7 of the Complaint.

8. On information and belief, Amneal admits that according to publically available FDA information, COLCRYS[®] was approved for marketing in the United States in 2009. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 8 of the Complaint.

9. Paragraph 9 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9 of the Complaint, and therefore denies them.

10. Paragraph 10 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 10 of the Complaint, and therefore denies the allegations.

A. Amneal admits that the ‘004 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics,” with a stated issue date of November 17, 2009, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10A of the Complaint.

B. Amneal admits that the ‘758 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout

Flares,” with a stated issue date of October 13, 2009, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10B of the Complaint.

C. Amneal admits that the ‘681 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of October 26, 2010, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10C of the Complaint.

D. Amneal admits that the ‘269 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of March 29, 2011, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10D of the Complaint.

E. Amneal admits that the ‘647 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of June 21, 2011, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10E of the Complaint.

F. Amneal admits that the ‘648 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of June 21, 2011, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10F of the Complaint.

G. Amneal admits that the ‘938 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of July 19, 2011, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10G of the Complaint.

H. Amneal admits that the ‘296 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics,” with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10H of the Complaint.

I. Amneal admits that the ‘297 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10I of the Complaint.

J. Amneal admits that the ‘655 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics,” with a stated issue date of January 17, 2012, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10J of the Complaint.

K. Amneal admits that the ‘395 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of April 9, 2013, naming on its face Matthew Davis and Hengsheng Feng as inventors. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10K of the Complaint.

L. Amneal admits that the ‘396 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of April 9, 2013, naming on its face Matthew Davis and Hengsheng Feng as inventors. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10L of the Complaint.

M. Amneal admits that the ‘721 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date

of May 14, 2013, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10M of the complaint.

N. Amneal admits that the ‘722 patent is entitled “Methods for Concomitant Administration of Colchicine and a Second Active Ingredient,” with a stated issue date of May 14, 2013, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10N of the Complaint.

11. Amneal admits that the ‘004, ‘758, ‘681, ‘269, ‘647, ‘648, ‘938, ‘296, ‘297, ‘655, ‘395, ‘396, ‘721 and ‘722 patents are collectively referred to in the Complaint as the “Patents.”

12. On information and belief, Amneal admits that according to publically available FDA information, certain patent information purportedly relating to NDA Nos. 22-351, 22-352 and 22-353 is included in the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly referred to as “the Orange Book”). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 12 of the Complaint.

13. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the patents asserted in the Complaint. Amneal denies that such asserted patents are valid and/or enforceable, and therefore, except as expressly admitted, Amneal denies the remaining allegations in paragraph 13 of the Complaint.

14. Paragraph 14 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, on information and belief, Amneal admits that according to publically available FDA information, COLCRYS[®] is indicated for the “prophylaxis and treatment of gout flares in adults” and “Familial Mediterranean fever

(FMF) in adults and children 4 years or older.” Except as expressly admitted, Amneal denies the remaining allegations in paragraph 14 of the Complaint.

15. Paragraph 15 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal denies the allegations in paragraph 15 of the Complaint.

16. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16 of the Complaint, and therefore denies them.

17. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 of the Complaint, and therefore denies them.

18. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 of the Complaint, and therefore denies them.

19. Denied.

20. Denied.

21. Paragraph 21 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal admits that it provided Takeda with an executed letter (“Amneal’s Paragraph IV Notice Letter”) dated February 20, 2013, providing notice that Amneal had filed ANDA No. 20-4711 seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS®, including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”), with respect to the ‘004, ‘758, ‘681, ‘269, ‘647, ‘648, ‘938, ‘296, ‘297, and ‘655 patents asserted in the Complaint. Further to the extent that a response is required, Amneal admits that its Paragraph IV Notice Letter asserts that all of the asserted patents in the Complaint are invalid and/or not infringed by Amneal’s 0.6 mg

oral tablet generic version of COLCRYS®. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 21 of the Complaint.

22. Paragraph 22 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal admits that it provided Takeda with an executed letter (“Amneal’s Paragraph IV Notice Letter”) dated May 31, 2013, providing notice that Amneal had filed ANDA No. 20-4711 seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS®, including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”), with respect to the ‘395 and ‘396 patents asserted in the Complaint. Further to the extent that a response is required, Amneal admits that its Paragraph IV Notice Letter asserts that all of the asserted patents in the Complaint are invalid and/or not infringed by Amneal’s 0.6 mg oral tablet generic version of COLCRYS®. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 22 of the Complaint.

23. Paragraph 23 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal admits that it provided Takeda with an executed letter (“Amneal Paragraph IV Notice Letter”) dated June 25, 2013, providing notice that Amneal had filed ANDA No. 20-4711 seeking marketing approval for a 0.6 mg generic version of COLCRYS®, including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”), with respect to the ‘721 and ‘722 patents asserted in the Complaint. Further to the extent that a response is required, Amneal admits that its Paragraph IV Notice Letter asserts that all of the asserted patents in the Complaint are invalid and/or not infringed by Amneal’s 0.6 mg oral tablet generic version of COLCRYS®. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 23 of the Complaint.

24. Paragraph 24 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 of the Complaint, and therefore denies them.

25. Denied.

26. Denied.

COUNT I

(Purported) Infringement of the '004 Patent Under 35 U.S.C. § 271 against Amneal

27. Amneal repeats its answers to paragraphs 1-26 as if fully set forth herein.

28. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the '004 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 28 of the Complaint.

29. Denied.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

COUNT II

(Purported) Infringement of the '758 Patent Under 35 U.S.C. § 271 against Amneal

34. Amneal repeats its answers to paragraphs 1-33 as if fully set forth herein.

35. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘758 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 35 of the Complaint.

36. Denied

37. Denied.

38. Denied

39. Denied.

40. Denied.

COUNT III

(Purported) Infringement of the ‘681 Patent Under 35 U.S.C. § 271 against Amneal

41. Amneal repeats its answers to paragraphs 1-40 as if fully set forth herein.

42. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘681 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 42 of the Complaint.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

COUNT IV

(Purported) Infringement of the ‘269 Patent Under 35 U.S.C. § 271 against Amneal

48. Amneal repeats its answers to paragraphs 1-47 as if fully set forth herein.

49. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘269 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 49 of the Complaint.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

54. Denied.

COUNT V

(Purported) Infringement of the ‘647 Patent Under 35 U.S.C. § 271 against Amneal

55. Amneal repeats its answers to paragraphs 1-54 as if fully set forth herein.

56. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘647 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2).

Except as expressly admitted, Amneal denies the remaining allegations in paragraph 56 of the Complaint.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

COUNT VI

(Purported) Infringement of the ‘648 Patent Under 35 U.S.C. § 271 against Amneal

62. Amneal repeats its answers to paragraphs 1-61 as if fully set forth herein.

63. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘648 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2).

Except as expressly admitted, Amneal denies the remaining allegations in paragraph 63 of the Complaint.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

COUNT VII

(Purported) Infringement of the ‘938 Patent Under 35 U.S.C. § 271 against Amneal

69. Amneal repeats its answers to paragraphs 1-68 as if fully set forth herein.

70. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘938 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 70 of the Complaint.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

COUNT VIII

(Purported) Infringement of the ‘296 Patent Under 35 U.S.C. § 271 against Amneal

76. Amneal repeats its answers to paragraphs 1-75 as if fully set forth herein.

77. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘296 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 77 of the Complaint.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

COUNT IX

(Purported) Infringement of the ‘297 Patent Under 35 U.S.C. § 271 against Amneal

83. Amneal repeats its answers to paragraphs 1-82 as if fully set forth herein.

84. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘297 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 84 of the Complaint.

85. Denied.

86. Denied.

87. Denied.

88. Denied.

89. Denied.

COUNT X

(Purported) Infringement of the ‘655 Patent Under 35 U.S.C. § 271 against Amneal

90. Amneal repeats its answers to paragraphs 1-89 as if fully set forth herein.

91. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘655 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 91 of the Complaint.

92. Denied.

93. Denied.

94. Denied.

95. Denied.

96. Denied.

COUNT XI

(Purported) Infringement of the ‘395 Patent Under 35 U.S.C. § 271 against Amneal

97. Amneal repeats its answers to paragraphs 1-96 as if fully set forth herein.

98. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘395 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 98 of the Complaint.

99. Denied.

100. Denied.

101. Denied.

102. Denied.

103. Denied.

COUNT XII

(Purported) Infringement of the '396 Patent Under 35 U.S.C. § 271 against Amneal

104. Amneal repeats its answers to paragraphs 1-103 as if fully set forth herein.

105. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the '396 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 105 of the Complaint.

106. Denied.

107. Denied.

108. Denied.

109. Denied.

110. Denied.

COUNT XIII

(Purported) Infringement of the '721 Patent Under 35 U.S.C. § 271 against Amneal

111. Amneal repeats its answers to paragraphs 1-110 as if fully set forth herein.

112. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘721 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 112 of the Complaint.

113. Denied.

114. Denied.

115. Denied.

116. Denied.

117. Denied.

COUNT XIV

(Purported) Infringement of the ‘722 Patent Under 35 U.S.C. § 271 against Amneal

118. Amneal repeats its answers to paragraphs 1-117 as if fully set forth herein.

119. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of the ‘722 patent. Amneal denies that the submission of ANDA No. 20-4711 constitutes an act of infringement under 35 U.S.C. §271(e)(2). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 119 of the Complaint.

120. Denied.

121. Denied.

122. Denied.

123. Denied.

124. Denied.

EXCEPTIONAL CASE

125. Amneal admits that prior to the filing of ANDA No. 20-4711, Amneal was aware of the existence of the '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396, '721, and '722 patents. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 125 of the Complaint.

126. Denied.

PRAYER FOR RELIEF

Amneal denies that Plaintiffs are entitled to the judgment and relief set forth in paragraphs (A) through (G) on pages 26-27 of the Complaint, or any relief for the allegations set forth in the Complaint.

II. AFFIRMATIVE DEFENSES

In further answer to the Complaint and as separate, affirmative defenses thereto, Amneal alleges as follows. Amneal expressly reserves the right to assert additional defenses that would be rendered appropriate in view of future discovery, information, and/or analysis.

First Affirmative Defense: Noninfringement

127. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '004 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

128. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '758 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

129. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '681 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

130. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '269 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

131. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '647 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

132. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '648 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

133. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '938 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

134. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '296 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

135. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '297 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

136. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '655 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

137. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '395 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

138. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '396 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

139. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '721 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

140. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '722 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

Second Affirmative Defense: Invalidity

141. Each and every claim of the '004 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

142. Each and every claim of the '758 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

143. Each and every claim of the '681 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

144. Each and every claim of the '269 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

145. Each and every claim of the '647 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

146. Each and every claim of the '648 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

147. Each and every claim of the '938 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

148. Each and every claim of the '296 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

149. Each and every claim of the '297 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

150. Each and every claim of the '655 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

151. Each and every claim of the '395 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

152. Each and every claim of the '396 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

153. Each and every claim of the '721 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

154. Each and every claim of the '722 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

Third Affirmative Defense: Prosecution History Estoppel

155. On information and belief Takeda is estopped from asserting any scope of the '004 patent that would cover Amneal's Product because of statements made during the prosecution of the application leading to the issuance of the '004 patent.

156. On information and belief Takeda is estopped from asserting any scope of the '758 patent that would cover Amneal's Product because of statements made during the prosecution of the application leading to the issuance of the '758 patent.

157. On information and belief Takeda is estopped from asserting any scope of the

‘681 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘681 patent.

158. On information and belief Takeda is estopped from asserting any scope of the ‘269 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘269 patent.

159. On information and belief Takeda is estopped from asserting any scope of the ‘647 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘647 patent.

160. On information and belief Takeda is estopped from asserting any scope of the ‘648 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘648 patent.

161. On information and belief Takeda is estopped from asserting any scope of the ‘938 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘938 patent.

162. On information and belief Takeda is estopped from asserting any scope of the ‘296 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘296 patent.

163. On information and belief Takeda is estopped from asserting any scope of the ‘297 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘297 patent.

164. On information and belief Takeda is estopped from asserting any scope of the ‘655 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘655 patent.

165. On information and belief Takeda is estopped from asserting any scope of the ‘395 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘395 patent.

166. On information and belief Takeda is estopped from asserting any scope of the ‘396 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘396 patent.

167. On information and belief Takeda is estopped from asserting any scope of the ‘721 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘722 patent.

168. On information and belief Takeda is estopped from asserting any scope of the ‘722 patent that would cover Amneal’s Product because of statements made during the prosecution of the application leading to the issuance of the ‘722 patent.

III. COUNTERCLAIMS

169. For its counterclaims against Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”), Counterclaimant Amneal Pharmaceuticals, LLC (“Amneal”) asserts that Amneal’s 0.6 mg colchicine product, as described and indicated in ANDA No. 20-4711, does not directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, infringe U.S. Pat. Nos. 7,619,004 (“the ‘004 patent”); 7,601,758 (“the ‘758 patent”); 7,820,681 (“the ‘681 patent”); 7,915,269 (“the ‘269 patent”); 7,964,647 (“the ‘647 patent”); 7,964,648 (“the ‘648 patent”); 7,981,938 (“the ‘938 patent”); 8,093,296 (“the ‘296 patent”); 8,093,297 (“the ‘297 patent”); 8,097,655 (“the ‘655 patent”); 8,415,395 (“the ‘395 patent”); 8,415,396 (“the ‘396 patent”); 8,440,721 (“the ‘721 patent”); and 8,440,722 (“the ‘722 patent”) (collectively “the patents-in-suit”), and/or such patents are invalid for failing to comply with one or more of the

provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

PARTIES

170. Counterclaimant Amneal Pharmaceuticals, LLC is a corporation organized under the laws of the State of Delaware, having a principal place of business at 440 U.S. Highway 22 East, Suite 104, Bridgewater, New Jersey 08807. Amneal is in the business of manufacturing, marketing and selling high quality pharmaceutical products in the United States, including the State of Delaware.

171. On information and belief, and as stated by the Plaintiff in its Complaint, Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

NATURE OF THE ACTION

172. The counterclaims herein arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under 21 U.S.C. § 355. Amneal seeks entry of a declaratory judgment order that the patents-in-suit are not infringed by Amneal’s 0.6 mg colchicine product for the indication described in its ANDA, and/or an order that patents-in-suit are invalid and unenforceable. Further, Amneal seeks entry of an order requiring Takeda to delete the ‘004, ‘758, ‘681, ‘269, ‘648, ‘296, ‘297, ‘655, ‘395, ‘396, ‘721 and ‘722 patents from the listing of patents in the “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly referred to as “the Orange Book”) for COLCRYS®.

JURISDICTION AND VENUE

173. This Court has jurisdiction over the asserted counterclaims under 28 U.S.C. §§ 1331, 1337(a) and 1338(a), the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, 35 U.S.C. § 1 *et seq.*, 21 U.S.C. § 355(c)(3)(D) and 21 U.S.C. § 355(j)(5)(c)(ii)(I).

174. Takeda has submitted to personal jurisdiction in this Court by bringing suit against Amneal in this Court. Venue is proper under 28 U.S.C. §§ 1391 and 1400, and as a result of Takeda's choice of forum.

175. The counterclaims encompass an action based on an actual controversy between Amneal and Takeda concerning the non-infringement and/or invalidity of the patents-in-suit, and/or improper Orange Book listing of the '004, '758, '681, '269, '648, '296, '297, '655, '395, '396, '721 and '722 patents.

BACKGROUND

176. The patents-in-suit, which are the subject of Amneal's counterclaims, are as follows:

A. The '004 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of November 17, 2009, naming on its face Matthew Davis as the inventor.

B. The '758 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout Flares," with a stated issue date of October 13, 2009, naming on its face Matthew Davis as the inventor.

C. The '681 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of October 26, 2010, naming on its face Matthew Davis as the inventor.

D. The '269 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of March 29, 2011, naming on its face Matthew Davis as the inventor.

E. The '647 patent is entitled on its face "Colchicine Compositions and Methods," with a stated issue date of June 21, 2011, naming on its face Matthew Davis as the inventor.

F. The '648 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of June 21, 2011, naming on its face Matthew Davis as the inventor.

G. The '938 patent is entitled on its face "Colchicine Compositions and Methods," with a stated issue date of July 19, 2011, naming on its face Matthew Davis as the inventor.

H. The '296 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor.

I. The '297 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor.

J. The '655 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of January 17, 2012, naming on its face Matthew Davis as the inventor.

K. The '395 patent is entitled on its face "Colchicine Compositions and Methods," with a stated issue date of April 9, 2013, naming on its face Matthew Davis and Hengsheng Feng as the inventors.

L. The '396 patent is entitled on its face "Colchicine Compositions and Methods," with a stated issue date of April 9, 2013, naming on its face Matthew Davis and Hengsheng Feng as the inventors.

M. The '721 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of May 14, 2013, naming on its face Matthew W. Davis as the inventor.

N. The '722 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of May 14, 2013, naming on its face Matthew W. Davis as the inventor.

177. On information and belief, based on statements made by Takeda in its Complaint, Takeda owns the patents-in-suit.

178. On information and belief, based on statements made by Takeda in its Complaint, Takeda owns NDA Nos. 22-351, 22-352 and 22-353 related to colchicine, sold in the U.S. under the name COLCRYS®.

179. On information and belief, based on statements made by Takeda in its Complaint, the FDA approved Takeda NDA No. 22-351 on July 30, 2009, NDA No. 22-352 on July 29, 2009, and NDA No. 22-353 on October 16, 2009.

180. On information and belief, certain patent information purportedly relating to NDA Nos. 22-351, 22-352 and 22-353 is included in the Orange Book: all of the patents-in-suit have been Orange Book listed by Takeda.

181. Amneal filed Abbreviated New Drug Application (“ANDA”) No. 20-4711 with the United States Food and Drug Administration (“FDA”), seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®] prior to the purported expiration of all of the patents-in-suit. Amneal provided Takeda with an executed letter (“Amneal’s Paragraph IV Notice Letter”) dated February 20, 2013, providing notice that Amneal had filed ANDA No. 20-4711 seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®], including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”), with respect to the patents asserted in the Complaint. In its Paragraph IV Notice Letter, Amneal averred that all of the asserted Takeda Orange Book patents are invalid and/or are not infringed by Amneal’s 0.6 mg oral tablet generic version of COLCRYS[®].

182. Takeda filed a patent infringement Complaint against Amneal in this Court on March 28, 2013, alleging infringement of all of the Orange Book listed patents.

183. Amneal provided Takeda with an executed letter (“Amneal’s Paragraph IV Notice Letter”) dated May 31, 2013, providing notice that Amneal had filed ANDA No. 20-4711 seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®], including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”), with respect to the ‘395 and ‘396 patents asserted in the Complaint. In its Paragraph IV Notice Letter, Amneal averred that all of the asserted Takeda Orange Book patents are invalid and/or are not infringed by Amneal’s 0.6 mg oral tablet generic version of COLCRYS[®].

184. Amneal provided Takeda with an executed letter (“Amneal’s Paragraph IV Notice Letter”) dated June 25, 2013, providing notice that Amneal had filed ANDA No. 20-4711 seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS[®], including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”), with

respect to the '721 and '722 patents asserted in the Complaint. In its Paragraph IV Notice Letter, Amneal averred that all of the asserted Takeda Orange Book patents are invalid and/or are not infringed by Amneal's 0.6 mg oral tablet generic version of COLCRYS®.

185. Amneal has denied that it has infringed, currently infringes or will infringe, directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit. Amneal has further asserted that the claims of the patents-in-suit are invalid for failure to satisfy one or more of the provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112.

186. Based on Takeda's filing of the Complaint, and Amneal's denial of Takeda's claims and Amneal's assertion of affirmative defenses, an actual controversy has arisen and now exists between the parties as to whether Amneal has infringed, is currently infringing or will infringe any valid and enforceable claim of the patents-in-suit, whether any of the patents-in-suit are valid, and whether certain of the patents-in-suit have been improperly listed in the Orange Book.

FIRST COUNTERCLAIM

Declaratory Judgment of Non-Infringement of the Patents-in-Suit

187. Amneal repeats and realleges paragraphs 169-186 as if fully set forth herein.

188. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '004 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

189. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '758 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

190. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '681 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

191. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '269 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

192. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '647 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

193. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '648 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

194. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '938 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

195. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '296 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

196. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '297 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

197. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '655 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

198. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '395 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

199. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '396 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

200. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '721 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

201. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '722 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

SECOND COUNTERCLAIM

Declaratory Judgment of Invalidity of the Patents-in-Suit

202. Amneal repeats and realleges paragraphs 169-201 as if fully set forth herein.

203. Each and every claim of the '004 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

204. Each and every claim of the '758 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

205. Each and every claim of the '681 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

206. Each and every claim of the '269 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

207. Each and every claim of the '647 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

208. Each and every claim of the '648 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

209. Each and every claim of the '938 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

210. Each and every claim of the '296 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

211. Each and every claim of the '297 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

212. Each and every claim of the '655 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

213. Each and every claim of the '395 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

214. Each and every claim of the '396 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

215. Each and every claim of the '721 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

216. Each and every claim of the '722 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD COUNTERCLAIM

Delisting of the '004, '758, '681, '269, '648, '296, '297, '655, '721 and '722 Patents

217. Amneal repeats and realleges paragraphs 169-216 as if fully set forth herein.

218. 21 U.S.C. § 355(j)(5)(c)(ii)(I) provides an ANDA holder with a counterclaim cause of action to seek an order requiring an NDA holder to delete patent information in an

Orange Book listing on the ground that the patent does not claim either the drug for which the NDA was approved or an approved method of using the drug.

219. COLCRYS® has been approved by the FDA as a single-ingredient oral colchicine product for the following indications:

- Prophylaxis and Treatment of Gout Flares in adults, and
- Familial Mediterranean fever (FMF) in adults and children 4 years or older.

220. COLCRYS® has been approved by the FDA with the following dosage and administration regimen:

- **Gout Flares:**
Prophylaxis of Gout Flares: 0.6 mg once or twice daily in adults and adolescents older than 16 years of age. Maximum dose 1.2 mg/day.
Treatment of Gout Flares: 1.2 mg (2 tablets) at the first sign of a gout flare followed by 0.6 mg (1 tablet) one hour later.”

221. The FDA approved usage codes for COLCRYS® are as follows:

- U-1007: Method of Treating Gout Flares;
- U-1020: Method for Using Colchicine for the Prophylaxis of Gout Flares;
- U-1116: Method of Administering Colchicine to Familial Mediterranean Fever Patients;
- U-1161: For the Treatment and Prophylaxis of Gout Flares & The Treatment of Familial Mediterranean Fever; and
- U-1166: A Method For Treatment of Gout Flares During Prophylaxis.

222. Takeda has listed the ‘004, ‘758, ‘681, ‘269, ‘648, ‘296, ‘297, ‘655, ‘721 and ‘722 patents in the Orange Book in relation to NDA Nos. 22-351, 22-352 and 22-353 and its colchicine product, sold in the U.S. under the name COLCRYS®.

223. The claims of each of the '004, '758, '681, '269, '648, '296, '297, '655, '721 and '722 patents recite methods for the concomitant administration of colchicine and a drug other than colchicine.

224. No claim of the '004, '758, '681, '269, '648, '296, '297, '655, '721 and '722 patents covers the drug colchicine or an approved method of using COLCRYS[®], based on the FDA approved indications, the approved dosage and administration statements and the usage codes stated for COLCRYS[®].

225. The listing of the '004 patent in the Orange Book for COLCRYS[®] should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

226. The listing of the '758 patent in the Orange Book for COLCRYS[®] should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

227. The listing of the '681 patent in the Orange Book for COLCRYS[®] should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

228. The listing of the '269 patent in the Orange Book for COLCRYS[®] should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

229. The listing of the '648 patent in the Orange Book for COLCRYS[®] should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

230. The listing of the '296 patent in the Orange Book for COLCRYS[®] should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

231. The listing of the '297 patent in the Orange Book for COLCRYS[®] should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

232. The listing of the '655 patent in the Orange Book for COLCRYS[®] should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

233. The listing of the '721 patent in the Orange Book for COLCRYS[®] should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

234. The listing of the '722 patent in the Orange Book for COLCRYS[®] should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

DEMAND FOR JUDGMENT

WHEREFORE, Amneal prays for the following relief:

A. Dismissal of all claims against Amneal with prejudice and denying all relief requested by Plaintiffs;

B. A declaration that Amneal has not infringed and will not infringe, directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner, any valid and enforceable claim of the patents-in-suit;

C. A declaration that Amneal has a lawful right to obtain FDA approval of its ANDA No. 20-4112 for its 0.6 mg colchicine product;

D. A declaration that Amneal has a lawful right to manufacture, use, import, market, sell and/or offer to sell its 0.6 mg colchicine ANDA product upon approval by the FDA;

E. A declaration that all claims of all of the patent-in-suit are invalid;

F. A declaration that the '004, '758, '681, '269, '648, '296, '297, '655, '721 and '722 patents are improperly listed in the Orange Book, including an order requiring that Plaintiff delist such patents with the FDA;

G. An injunction enjoining the Plaintiff, their officers, employees, agents, representatives, attorneys and others acting on their behalf, from threatening or initiating infringement litigation against Amneal or its customers, dealers or suppliers, doctors, patients, or

any prospective or present sellers, dealers, distributors or customers of Amneal, or charging them either orally or in writing with infringement of any of the patents-in-suit;

H. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Amneal is entitled to recover its reasonable attorney's fees and costs upon prevailing in this action; and

I. An award to Amneal of such further relief as this Court may deem necessary, just and proper.

Dated: September 9, 2013

By: /s/ Mary B. Matterer
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